



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

CERTIFIED MAIL
RECEIPT REQUESTED

December 7, 2010

Apex Wellness Group, LLC
(dba) pHion Balance
c/o Mr. David Whelan, Founder
14362 North Frank Lloyd Wright Blvd.; Suite 1000
Scottsdale, AZ 85260

Dear Mr. Whelan:

This is to advise you that the U. S. Food and Drug Administration (henceforth called "FDA") has reviewed your web site at the Internet addresses <http://www.ph-ion.com> and has determined that the products, "pHion Whole Body Detoxification" and "pHion Silvagen", are promoted for conditions that cause the product to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (henceforth called "the Act") [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

For "pHion Whole Body Detoxification":

Under the heading, "Highlights":

- "...detoxify the Liver, Lymph and Kidneys"
- "Eradicates Mycotoxins, Exotoxins, and Endotoxins"
- "...Eliminate Candida, Yeast, and Fungus"

Under the heading, "Reasons to buy":

- "...blend of herbal extracts and dietary ingredients that kill yeast, fungi and harmful organisms."
- "Not only does pHion Whole Body Detoxification eliminate microforms from your system, it also gets rid of the toxins they secrete."

- “Whole Body Detoxification neutralizes and eliminates toxins in the liver, lymph, and kidneys, so all your detoxification pathways will be working at peak performance.”

Under the heading, “Product Details”:

- “...eliminate bacteria, yeast, and fungus as well as the toxins they produce.”
- “Calcium Undecylenate, Caprylic Acid, Grapefruit Seed Extract, Olive Leaf Extract. These ingredients act as...[a] broad-spectrum anti-yeast and anti-fungal formula.”
- “Calcium Undecylenate helps to stop the unwanted proliferation of Candida...”
- “Caprylic acid has antifungal properties, and has been shown to ward off yeast, especially Candida strains.”
- “Grapefruit Seed Extract has been shown to be effective in eradicating Candida, salmonella, E. Coli, parasites and fungus.”
- “Olive Leaf Extract destroys harmful bacteria and microbes.”
- “...ingredients support enhanced liver detoxification.”
- “...removal of toxins from the body, and cleansing of the kidneys.”
- “Marshmallow Root is used in treating irritated tissues in urinary tract infections, and inhibits bacterial growth.”
- “Gravel Root increases the removal of waste by the kidneys, and helps prevent the formation of kidney stones.”

For "pHion Silvagen" under the heading “pHion Silvagen”:

- “Safely targets and eradicates harmful bacteria! pHion Silvagen works by cutting off harmful microforms’ energy supply! So say goodbye to acid-causing microforms, with the extensively tested colloidal silver formula, pHion Silvagen.”
- In your response to a question about pHion Silvagen which asked, “Does colloidal silver help fight candida or bacteria infection?” you state: “Thank you for your question. Yes, this will kill both bacteria and help eliminate candida. We also have a great product called the pHion Detox that eliminates candida/yeast.”

In the FAQ section of your website, under “pHion Whole Body Detoxification”:

- “...this is a full body detox. This product is great for elimination of yeast and fungus overgrowth. By taking this product you are fully eliminating the buildup of toxins throughout your body.”
- “...pHion Whole Body Detoxification helps to eliminate bacteria, yeast, and fungus as well as the toxins they produce.”
- “This product will detoxify your liver, lymph, kidneys and rid your body of yeast and fungus. If you are experiencing problems in any of these areas then this is the supplement you should choose.”

In the FAQ section of your website, under “pHion Silvagen”:

- “pHion Silvagen is a natural antibiotic and preventative against infections... The result is the destruction of disease-causing organisms in the body...”
- “pHion Silvagen is lethal to bacteria, yeasts and some viruses.”

We also note that FDA picked up promotional material for your products at the 2010 Natural Products Expo East trade show that was held on October 14-16, 2010 at the Boston Convention & Exhibition Center. Claims included in the promotional literature include the following:

On a page titled, “Individual Product Highlights”, we note the following claims:

Under the heading, “pHion Whole Body Detoxification”:

- “Eliminates yeast, fungi, and bacteria”
- “Eliminates mycotoxins, Endotoxins, and Exotoxins”
- “Detoxifies the liver, lymph and kidneys”

Claims in flyers, brochures and other promotional labeling that promotes your product for use in the cure, mitigation, treatment, or prevention of disease may establish that your product is a drug. Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, these products are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or

prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. Please respond, in writing, with fifteen (15) days to:

Jennifer A. Thomas (Director of Division of Enforcement)
Office of Compliance
c/o Seyra Hammond (Compliance Officer)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

and

Blake Bevill
Director of Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2506

Sincerely,

/s/

Alonza Cruse
District Director
Los Angeles District